REMARKS

In response to the Office Action mailed December 22, 2003 (hereafter referred to as "Office Action"), Applicant respectfully requests re-examination of the claims and reconsideration of the Examiner's final rejection of the claims of the above-identified application.

Claims 1-20 are pending in the Application.

Claims 1, 6, 17, and 18 have been amended.

Claim 2 has been cancelled herein.

INTERVIEW WITH EXAMINER

Pursuant to Applicant's April 9, 2004 interview with Examiner Choi, Applicant has amended claim 1 to require at least about 10% (w/v) pre-treated ascorbic acid, having a pH of 3.5 to 4.1, and not having any chemical stabilizers; and claims 17 and 18 to require at least about 5.0% (w/v) pre-treated ascorbic acid, having a pH of 3.5 to 4.1, and not having any chemical stabilizers. Attached hereto as Exhibit A is a copy of the Affidavit of Edward T. Mickelson filed concurrently with the AF response to Applicant's co-pending application Serial No. 09/990,611.

REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 1-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Schinitsky et al. ("*Schinitsky*") (U.S. Patent 4,938,969) in view of Murad ("*Murad*") (U.S. Patent 5,804,594), Herstein ("*Herstein*") (U.S. Patent 5,902,591) and Taylor et al. ("*Taylor*") (U.S. Patent 5,308,621). Reconsideration and withdrawal of the rejections are respectfully requested in view of the above-mentioned interview and in view of the following remarks and amendments.

The Examiner states that *Schinitsky*, *Murad*, *Herstein*, and *Taylor* were discussed in a prior Office Action (Applicant assumes the Examiner is referring to the third Office Action mailed December 3, 2002) and that such discussion has been incorporated into the present Office Action. The Examiner further states that Applicant's arguments have been duly considered, but are deemed unpersuasive. The Examiner also notes that Applicant has argued that the prior art does not teach a pH of above 3.5. However, the Examiner states that *Herstein* (column 2, lines

40-47, and column 10, lines 6-17) teaches that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule. *See* Office Action, page 3.

In order to establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300, 1301 (Bd. Pat. App. & Int. 1993); *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 U.S.P.Q. 657 (Fed. Cir. 1985). The legal conclusion of obviousness must be supported by facts. See *Graham v. John Deere & Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). Where the legal conclusion is not supported by facts, it cannot stand. *Id.* A rejection based on § 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. The patentability of an invention is not to be viewed with hindsight or "viewed after the event." *Goodyear Company v. Ray-O-Vac Company*, 321 U.S. 275, 279, 64 S.Ct. 593, 88 L.Ed. 721 (1944). The proper inquiry is whether bringing them together was obvious and not, whether one of ordinary skill, having the invention before him, would find it obvious through hindsight to construct the invention. Accordingly, an Examiner cannot establish obviousness by locating references which describe various aspects of the patent Applicants' invention without also providing objective evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. An Examiner's unsupported opinion is not objective evidence.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants'

disclosure. *See* MPEP § 2143. *See also In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

Claim 1 (and claims depending therefrom) has been amended to require a composition comprising at least about 10% (w/v) pre-treated ascorbic acid, having a pH of 3.5 to 4.1, and not having any chemical stabilizers; an aminosugar; and water. Claim 17 (and claims depending therefrom) has been amended to require a composition for treating an inflammatory skin ailment, the composition comprising: at least about 5.0% (w/v) pre-treated ascorbic acid; at least about 10% (w/v) glucosamine; a non-toxic zinc salt; a tyrosine compound; and water, wherein the composition has a pH of 3.5 to 4.1 and does not have any chemical stabilizers. Claim 18 (and claims depending therefrom) has been amended such that it now discloses a method of treating rosacea or other inflammatory skin affliction, the method comprising topically applying to the afflicted skin a composition comprising at least about 5.0% (w/v) pre-treated ascorbic acid; at least 10% (w/v) glucosamine or other anti-inflammatory aminosugar; and water, wherein the composition has a pH of 3.5 to 4.1 and does not have any chemical stabilizers.

Claim 2 has been cancelled.

Schinitsky discloses a composition comprising from about 2 to about 20% ascorbic acid, about 1 to about 10% tyrosine, and about 0.5 to about 5% zinc sulfate. *See Schinitsky*, column 2, lines 38-45. Applicant contends, however, that *Schinitsky* does not anticipate, disclose, or suggest Applicant's composition as disclosed in Applicant's independent claims 1 and 17, and the claims depending therefrom, wherein such claims require an aqueous composition of at least 5.0% (w/v) pre-treated ascorbic acid (10% in the case of claim 1) and having a pH of 3.5 to 4.1. Applicant respectfully suggests that *Schinitsky* does not disclose or suggest various features of Applicant's claim(s), particularly a composition having a pH of 3.5 to 4.1. Examiner's attempts to remedy the deficiencies of *Schinitsky* by combining with three other references, *Murad*, *Herstein*, and *Taylor*, to arrive at Applicant's claimed invention, still fall short of an aqueous composition of at least 5.0% (w/v) pre-treated ascorbic acid and having a pH of 3.5 to 4.1. Furthermore, none of these references, either alone or in combination, teach a method for treating rosacea, as put forth in Applicant's claim 18 and claims depending therefrom.

Murad discloses a composition comprising at least four components: a sugar compound, a primary antioxidant component, at least one amino acid component, and at least one transition metal component. *See Murad*, column 3, lines 25-35. Further, *Murad* prefers an embodiment where the composition is administered orally. In fact, all Examples in *Murad* are directed to compositions in either tablet or capsule form. In a preferred *Murad* embodiment, the composition is administered as a tablet or capsule having about 1 mg to 2,000 mg of *Murad* composition. *See Murad*, column 4, lines 39-50. Further, *Murad* discloses that although any suitable route of administration may be employed, oral administration is preferred. *See Murad*, column 8, lines 43-52. Further, all three routes of administration of the *Murad* composition disclosed in the *Murad* examples comprise orally administrated forms such as capsules (*Murad* Example 1), soft gelatin capsules (*Murad* Example 2), and tablets (*Murad* Example 3). *See Murad*, column 10, lines 5-32. Further, *Murad* claim 1 discloses an orally administered pharmaceutical composition comprising the following *Murad* components: a sugar compound; a primary antioxidant component; at least one amino acid component; and at least one transition metal component. *See Murad*, claim 1. Applicant respectfully suggests that the *Murad* emphasis on oral administration, specifically capsules, soft gelatin capsules, and tablets, teaches away from Applicant's composition having a pH of more than 3.5. Applicant also respectfully suggests that since *Murad* is preferably administered orally, pH is not a critical feature of the *Murad* composition and actually teaches away from Applicant's composition, as discussion of pH, being a measure of the hydronium-ion concentration, is limited to solution-based compositions and is not relevant to the solid-based compositions of *Murad's* tablets and capsules. In fact, pH values have little relevance outside the realm of aqueous-based solutions. Thus, compositions of *Murad* delivered orally in soft gelatin capsules (Example 2) comprising an oil (in which ascorbic acid is only very slightly soluble) are more likely suspensions of ascorbic acid particles, wherein pH again has no relevance. Furthermore, no method of treating rosacea is put forth in *Murad*.

Herstein discloses a composition comprising two phases. The first *Herstein* phase is a powder phase containing ascorbic acid. The second *Herstein* phase is a liquid emulsion phase containing a stabilizing effective amount of an organoclay composition. *See Herstein*, column 2, line 65 - column 3, line 6. *Herstein* discloses in great detail the two phases. *Herstein* discloses that the liquid phase comprises an emulsifier that can be selected from various emulsifiers. *See*

Herstein, column 4, line 31 - column 6, line 19. *Herstein* maintains that the pH of the combined two-phase composition is preferably maintained within a pH range of 3.5-4.1. *Herstein* further maintains that greater than 82% of the ascorbic acid in his composition remains in the protonated (i.e., ascorbic acid) form. Yet, *Herstein* describes using species such as triethanol amine, sodium hydroxide, and ammonium hydroxide to modulate the pH and maintain it at desired levels. *See Herstein*, column 10, lines 6-23. Applicant contends that the addition of such bases will serve to deprotonate the ascorbic acid, yielding the unstable ascorbate anion. Furthermore, the organoclays described in *Herstein* comprise amine salts that can be expected to complex the ascorbate anion. Thus, while such formulations of *Herstein* are novel in their use of such organoclays to stabilize the ascorbate anion, they cannot be said to comprise at least 5% ascorbic acid, because such ascorbic acid has been deprotonated. Note that *Herstein* provides no empirical evidence for his above-described claim of 82% protonated ascorbic acid in his compositions. Furthermore, *Herstein* fails to teach a tretment for rosacea.

Taylor discloses the transdermal delivery of micro-sized particles of ascorbic acid. Such micro-sized particles of ascorbic acid are "predominately sized below 20 microns [μm]. More preferably they are predominately in the range of from 2-10 microns." *See Taylor*, column 1, lines 52-55. Such particles are dispersed in a carrier such that "the portion of acetic acid [as particulates] in solution will be less than 0.1% by weight of the composition." *See Taylor*, column 1, lines 59-60. A number of suitable non-aqueous carriers are listed (column 2, lines 20-26) and it is stated that "[p]referably the carrier is essentially water free containing less than about 0.5% by weight water." *See Taylor*, column 2, lines 35-37. The only similarity this reference has with the present Application is the presence of ascrobic acid, albeit in a particulate (solid) form. As in the foregoing remarks, *Taylor* also fails to teach a tretment for rosacea.

Applicant respectfully suggests that there is no motivation or suggestion to combine or modify any of the above-mentioned references. Further, even if there were such motivation or suggestion, one could not arrive at the Applicant's claimed invention comprising a composition comprising an at least about 5%(w/v) aqueous solution of pre-treated ascorbic acid with a pH of 3.5 to 4.1. While some of the above-mentioned references teach compositions comprising greater than 5% ascorbic acid, such compositions comprise pH values below 3.5 or are in a form in which pH is not relevant (e.g., a tablet); and while some of the above-mentioned references

teach compositions with pH values greater than 3.5, such compositions do not comprise greater than 5% ascorbic acid; none of the above-mentioned references, either alone or in combination, teach or suggest a 5% ascorbic acid solution with a pH greater than 3.5. In the absence of treatments described in the present Application, a 5%(w/v) aqueous solution of ascorbic acid will not be stable at pH values greater than 3.5. Furthermore, none of the above-mentioned references, either alone or in combination, teach a method for treating rosacea.

In conclusion, Applicant respectfully requests that this Application be re-examined in light of the above remarks. Applicant further respectfully requests that the rejections under 35 U.S.C. § 103 be withdrawn and that the claims remaining in the Application be allowed.

Since new claims have not been added, no additional filing fees are believed to be due. Enclosed is a Petition for One-Month Extension of Time to File the response, along with a check in the amount of $55.00 for the Extension fee. It is believed that no further fees are due; however, the Director is hereby authorized to charge any fees or credit any overpayment to Deposit Account Number 23-2426 of WINSTEAD SECHREST & MINICK P.C. (referencing number 41758-P001P2X1).

If the Examiner has any questions or comments concerning this paper or the present application in general, the Examiner is invited to call the undersigned at (214) 745-5710.

Respectfully submitted,
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